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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/698,205	10/31/2003	Frank Forrest Humbles		9994
7590 11/08/2010 Michael E. Mauney			EXAMINER	
Attorney at Law			MAYO-PINNOCK, TARA LEIGH	
P. O. Box 10266 Southport, NC 28461			ART UNIT	PAPER NUMBER
•			3671	
			MATERIAL TO A STATE OF THE STAT	DET HERWINGSE
			MAIL DATE	DELIVERY MODE

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Application No. 10/698,205 HUMBLES, FRANK FORREST Examiner Art Unit 3671 - The MAILING DATE of this communication appears on the cover sheet with the correspondence address -eriod for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13(a). In no event, however, may a reply be timely filled after Six (b) MONTHS from the mailing date of this communication.

The MAILING DATE of this communication appea Period for Reply	rs on the cover sheet with the correspondence address
WHICHEVER IS LONGER, FROM THE MAILING DAT  - Extensions of time may be available under the provisions of 37 CFR 1.136( after SIX (6) MONTHS from the mailing date of this communication.	
<ul> <li>Failure to reply within specialled above, the hazimin statutory period will.</li> <li>Failure to reply within the set or extended period for reply will, by statute, can Any reply received by the Office later than three months after the mailing da earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>	use the application to become ABANDONED (35 U.S.C. § 133).
Status	
1) Responsive to communication(s) filed on 13 Aug.	ust 2010.
2a)⊠ This action is FINAL. 2b)□ This ac	ction is non-final.
3) Since this application is in condition for allowance	e except for formal matters, prosecution as to the merits is
closed in accordance with the practice under Ex	parte Quayle, 1935 C.D. 11, 453 O.G. 213.
Disposition of Claims	
4) Claim(s) 1.3-10 and 12-15 is/are pending in the a	application.
4a) Of the above claim(s) 13-15 is/are withdrawn	from consideration.
5) Claim(s) is/are allowed.	
6)⊠ Claim(s) <u>1,3-10 and 12</u> is/are rejected.	
7) Claim(s) is/are objected to.	
8) Claim(s) are subject to restriction and/or e	lection requirement.
Application Papers	
9) The specification is objected to by the Examiner.	
10) The drawing(s) filed on 31 October 2003 is/are: a	ı)⊠ accepted or b)⊡ objected to by the Examiner.
Applicant may not request that any objection to the dra	awing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction	is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) The oath or declaration is objected to by the Exam	niner. Note the attached Office Action or form PTO-152.
Priority under 35 U.S.C. § 119	
12) Acknowledgment is made of a claim for foreign pr a) All b) Some * c) None of:	iority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some c) None of.  1. Certified copies of the priority documents h	nave been received
Certified copies of the priority documents F      Certified copies of the priority documents F	
	documents have been received in this National Stage
application from the International Bureau (I	
* See the attached detailed Office action for a list of	
	·
Attachment(s)	
) Notice of References Cited (PTO-892)	4) Interview Summary (PTO-413)
Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date

Attachment(s)		
Notice of References Cited (PTO-892)     Notice of Draftsperson's Patent Drawing Review     Information Discosure Statement(s) (PTO/Sbroe Paper No(s)/Mail Date	(PTO-948) Pape	riew Summary (PTO-413) r No(s)/Mail Date. e of Informal Patent Application
U.S. Patent and Trademark Office PTOL-326 (Rev. 08-06)	Office Action Summary	Part of Paper No./Mail Date 20101103

Application/Control Number: 10/698,205 Page 2

Art Unit: 3671

### DETAILED ACTION

### Election/Restrictions

 Newly submitted claims 13 through 15 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: they are directed a method of protecting a patient's arms.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 13 through 15 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

# Claim Objections

The prior objections to claims 1, 7 and 10 for minor informalities have been overcome by the response filed 13 August 2010.

### Claim Rejections - 35 USC § 112

3. The prior rejections of claims 1, 3 through 6, 8 through 10 and 12 under 35 U.S.C. 112, second paragraph have been overcome by the response filed 13 August 2010.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all
obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole ownld have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

 Claims 1, 3 through 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vinci (U.S. Patent No. 5,542,121 A) in view of Gabriele et al. (U.S. Patent No. 4,030,719 A) and Tari (U.S. Patent No. 4,662,366 A).

Vinci '121, as best seen in Figures 6 and 7, shows an arm protection apparatus for positioning a patient's arms (11) when in a prone or supine position on a patient support comprising:

with regard to claims 1 and 7,

- (a) a one-piece pad with a central portion (11) positionable under the patient's body;
- (d) on said one-piece pad, a right arm lower section positionable around a lower right arm of a patient including means for attaching said right arm lower section to said central portion of said one-piece pad so that said right arm lower section is folded around a patient's lower arm; and
- (e) on said one-piece pad, a left arm lower section positionable around a lower left arm of a patient including means for attaching said left arm lower section to said central portion of said one-piece pad so that said left arm lower section is folded around a patient's lower left arm; with regard to claims 3 and 10,

wherein said right and left means for are hook and loop fasteners (Claim 2); and with regard to claims 4 and 9,

wherein said one-piece pad is radiolucent (col. 5, lines 33 through 37).

Application/Control Number: 10/698,205 Art Unit: 3671

Vinci '121 fails to teach:

with regard to claims 1 and 7,

the one-piece pad being a foam pad; upper right and upper left arm sections; and

a preperforated tear-away portion;

with regard to claim 5,

the one-piece pad being generally H-shaped

with regard to claim 6,

the general H-shape having a width approximately equal to the length of a patient's torso; and

with regard to claim 12,

four arm section one-piece foam pads attached to the central one-piece foam pad, each arm section one-piece foam pad sized to fit around approximately one-half of a patient's arm.

Gabriele et al. '719 disclose a restraining device for immobilizing patients during radiological examination, the device including restraints comprising straps made of fabric having foam attached to one surface (Claim4; and col. 3, lines 40 through 47).

Tari '366, as seen in Figures 1 through 4, shows an arm support (10) for a patient's arms comprising left and right upper and lower assemblies (30 and 32) positionable about the upper and lower sections (18 and 22) of an arm of a patient (14), the upper and lower assemblies configured to immobilize the entire arm of a patient (col. 3, lines 62 through 67), wherein each of

Art Unit: 3671

the upper and lower sections includes means for attaching (45 and 46); the left and right upper and lower sections including four one-piece arm sections (38, 38').

With regard to claims 1 and 7, it would have been obvious to one having ordinary skill in the art of patient supports at the time the invention was made to make the one-piece pad of Vinci '121 a foam pad as taught by Gabriele et al. '719 to increase the comfort of the pad.

Specifically, one having ordinary skill in the art would have had a reasonable expectation of success, since the modification would have merely required the addition of a known element for its intended purpose of restraining a patient.

With regard to claims 1, 5, 7 and 12, it would have been obvious to one having ordinary skill in the art of patient supports at the time the invention was made to modify the one-piece pad disclosed by Vinci '121 such that the right and left arm sections would each include upper and lower sections as taught by Tari '366 to provide support for both the upper and lower sections of a patient's arms. Specifically, one having ordinary skill in the art would have had a reasonable expectation of success, since the modification would have merely required the duplication of parts in a known manner.

With regard to claims 1 and 7, while the combination of Vinci '121, Gabriele et al. '719 and Tari '366 fails to teach a perforated tear-away portion, it would have been an obvious modification for one of ordinary skill in the art at the time of invention to provide the prior art apparatus with a perforated tear-away portion since the examiner takes Official Notice of known use of the same in the medical arts to provide exposure to a part of a patient.

Art Unit: 3671

With specific regard to claims 1 and 7, the term "preperforated" has not been given patentable weight since the method of forming an apparatus is not germane to the patentability of the apparatus itself. For the purpose of prosecution on the merits, the examiner has interpreted the term "preperforated" to simply mean --perforated--.

With regard to claim 6, a one-piece pad having a width approximately equal to the length of a patient's torso is inherent to the device taught by the combination of Vinci '121, Gabriele et al. '719 and Tari '366.

# Response to Arguments

 Applicant's arguments filed 13 August 2010 have been fully considered but they are not persuasive.

Applicant generally argues the arm protection apparatus taught by the combination of prior art cannot be used during an operative procedure to secure and protect the patient's arms from injury from pressure or gravity. The examiner contends none of claims 1, 3 through 10 and 12 recites language relating to injury of a patient resulting from pressure or gravity and any arguments based on features or functions which are not recited are not pertinent to the rejection of the claims.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the

Art Unit: 3671

applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

## Response to Amendment

7. The declaration of Frank Forrest Humbles under 37 CFR 1.132 filed 13 August 2010 is insufficient to overcome the rejection of claims 1, 3 through 10 and 12 based upon the Vinci '121 reference set forth in the last Office action because:

It does not provide a successful showing of long-felt need. Specifically, Declarant fails to set forth evidence showing unsuccessful efforts to solve the problem. See *Orthopedic Equipment Co., Inc. v. All Orthopedic Appliances, Inc.,* 707 F.2d 1376, 217 USPQ 1281 (Fed. Cir. 1983). Additionally, Declarant states "I recognized there was a need..." This statement contradicts a showing of long-felt need. See *In re Gershon,* 372 F.2d 535, 152 USPQ 602 (CCPA 1967).

It does not provide a successful showing of commercial success. Specifically, Declarant fails to establish a nexus between the claimed features of the invention and the commercial success. See MPEP 716.03(a).

8. The declaration of Thomas Holt under 37 CFR 1.132 filed 13 August 2010 is insufficient to overcome the rejection of claims 1, 3 through 10 and 12 based upon the Vinci '121 reference set forth in the last Office action because: It does not provide a successful showing of long-felt need. Specifically, Declarant makes allegations in paragraph 4 and states his opinion in

Art Unit: 3671

paragraph 5. Additionally, Declarant fails to set forth any evidence showing unsuccessful efforts to solve the problem.

- 9. The declaration of Paul L. Sasser under 37 CFR 1.132 filed 13 August 2010 is insufficient to overcome the rejection of claims 1, 3 through 10 and 12 based upon the Vinci '121 reference set forth in the last Office action because: It does not provide a successful showing of long-felt need. Specifically, Declarant makes allegations in paragraph 4 and states his opinion in paragraph 5. Additionally, Declarant fails to set forth any evidence showing unsuccessful efforts to solve the problem.
- 10. The declaration of William L. Mills under 37 CFR 1.132 filed 13 August 2010 is insufficient to overcome the rejection of claims 1, 3 through 10 and 12 based upon the Vinci '121 reference set forth in the last Office action because: It does not provide a successful showing of long-felt need. Specifically, Declarant makes allegations in paragraph 4 and states his opinion in paragraph 5. Additionally, Declarant fails to set forth evidence showing unsuccessful efforts to solve the problem.

### Conclusion

 THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 3671

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TARA MAYO-PINNOCK whose telephone number is (571) 272-6992. The examiner can normally be reached on Monday through Friday 8:30 AM to 5:00 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas B. Will can be reached on 571-272-6998. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TARA MAYO-PINNOCK/ Primary Examiner, Art Unit 3671

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04 November 2010